IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** *Carolyn Lewis, et al. v. Johnson & Johnson, et al.* Case No. 2:12-cv-04301	**Master File No. 2:12-md-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

BENCH MEMORANDUM OF DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON REGARDING SUFFICIENCY OF EVIDENCE AS TO UNREASONABLE DANGEROUSNESS, SAFER ALTERNATIVE DESIGN, AND SPECIFIC CAUSATION

No expert has offered the opinion to a reasonable degree of scientific or medical certainty that TVT was unreasonably dangerous and that a specific alternative design, equally effective as TVT in the treatment of SUI, was available and feasible in 2009 and would have prevented or reduced the risk of the specific injury Carolyn Lewis claims. Indeed, the only testimony in the record is that any of the non-specific "alternative designs" discussed by Plaintiff's experts do not work for the treatment of SUI. In addition, no expert has testified that Plaintiff's injuries were caused by a defect in the TVT. For these reasons, her claims fail as a matter of law.

To prevail, Plaintiff must prove that a specific defect existed in the design of TVT that made it "unreasonably dangerous," and that this alleged defect was a producing cause of her alleged injury. *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 738 (N.D. Tex. 2000); *Romo v. Ford Motor Co.*, 798 F. Supp. 2d 798, 806 (S.D. Tex. 2011). A product is not "unreasonably dangerous if there is no safer alternative design that addresses that defect. That is, Plaintiff must also prove that a safer but equally efficacious alternative design that addresses the defect was available and feasible in 2009 and that this alternative design would have significantly reduced the risk of the injury Plaintiff allegedly sustained. *Smith v. Louisville Ladder Corp.*, 237 F.3d 515, 519-20 (5th Cir. 2001). All three elements require expert testimony because they all involve issues beyond the experience and understanding of laypersons. *See id.* at 809; *Kallassy v. Cirrus Design Corp.*, 2006 U.S. Dist. LEXIS 34347, at *10-11 (N.D. Tex. May 30, 2006).

I. Plaintiff Failed To Show A Specific Defect In The TVT Design.

Several risk-utility factors inform whether a product is unreasonably dangerous, such as:

> the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use; . . . [and] the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs.

Dyer v. Danek Med., Inc., 115 F. Supp. 2d 732, 738 (N.D. Tex. 2000). Whether a product is

unreasonably dangerous is a question of law "if reasonable minds cannot differ on the risk-utility analysis considerations." *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 260-61 (Tex. 1999). Here, Plaintiff's proof does not permit a reasonable juror to find the TVT unreasonably dangerous.

Plaintiff alleges three defects: (1) TVT is too heavy and the pores are too small (2/10 RT 103:20-23); (2) it "ropes and frays and curls up and loses particles" in vivo (2/10 RT 104:2-3); and (3) it degrades (2/10 RT 104:6-7). Plaintiff presented no evidence that Mrs. Lewis's TVT implant roped, frayed, or curled up, so the Court need not consider those theoretical defects. While Plaintiff made some effort to claim that her explant had lost particles, the expert testimony was speculative at best. Dr. Jordi, Plaintiff's chemistry expert, reported flaking and cracking from his visual inspection of Plaintiff's explant, but he did not opine that the supposed flaking and cracking rendered TVT unsuitable for its intended purposes. (2/12 RT 130:22-131:4). And Plaintiff's experts could not link any evidence of degradation or particle loss to Ms. Lewis. (2/11 RT 99:23-100:19; 2/13 RT 102:22-25; 2/13 RT 103:19-22).

That leaves only the weight and pore size of the mesh as a potential defect relevant in this case. Plaintiff's evidence fails on those as well. None of Plaintiff's experts testified that the mesh used in the TVT rendered the device unsafe. Dr. Klosterhalfen testified that in his review of explants, he saw the same complications in large-pore, lightweight meshes as he saw in small-pore, heavyweight meshes. (Klosterhalfen 182:24-184:8). He also could not testify to a reasonable degree of medical probability that larger-pore meshes would be effective for treating SUI. (Klosterhalfen 45:14-19, 180:19-20).

None of the experts therefore testified that any defect rendered the TVT unreasonably dangerous. At best, Plaintiff can only show her paid experts' disagreement with the vast majority of the medical community. As Dr. Rosenzweig acknowledged, TVT has been endorsed

as a safe and acceptable SUI treatment by the American Urogynecology Society (AUGS), the International Urogynecology Society, and the American Urology Society. (2/11 RT 158:11-159:8). TVT is the most widely used surgical treatment for SUI. (2/11 RT 127:2-7). Indeed, 99% of AUGS members use midurethral slings to treat SUI. (2/11 RT 126:17-22). Dr. Zimmern admitted that the vast majority of surgeons use midurethral slings to treat SUI. (Zimmern 152:24-155:11). More telling still, Dr. Klinge co-authored a book chapter in 2010 calling TVT the "gold standard" to treat SUI. (2/13 RT 105:1-25).

II. Plaintiff Failed To Show That A Safer But Equally Efficacious Alternative Design Was Available In 2009 And Would Have Significantly Reduced The Risk of Her Injury.

To prevail, Plaintiff must prove that a safer but equally efficacious alternative design would have significantly reduced the risk of injury was available and feasible in 2009. She has vacillated between four theories: (1) PVDF mesh, (2) Ethicon hernia meshes, e.g., Vypro or Ultrapro, (3) modified Prolene, and (4) native tissue repair. None of these suffices. Not a single one of Plaintiff's experts testified to a reasonable degree of medical certainty that PVDF, a hernia mesh, or a modified Prolene is a safer alternative design that would have significantly reduced the risk of her alleged injury. The only testimony in the record is that none of these non-specific "alternative designs" discussed by Plaintiff's experts work for the treatment of stress urinary incontinence. And native tissue repair cannot constitute an alternative design as a matter of law because it is not a design, but rather requires the product not be used at all.

PVDF mesh. No expert has testified that PVDF mesh is a safer alternative design to the TVT. Dr. Klosterhalfen was asked, but did not opine in the videotaped clip that, to a reasonable degree of medical probability, PVDF mesh was a feasible alternative to TVT in treating SUI. (Klosterhalfen 25:25-26:07). Nor did Dr. Klinge so opine.

Dr. Klosterhalfen says that PVDF mesh has sufficient "effective porosity" and the TVT

mesh does not. But he has failed to equate safe meshes with "effective porosity." The "effective porosity" concept was developed by Plaintiff's experts in this case and there are no clinical studies regarding the biocompatibility of this theory. (Klosterhalfen 199:5-15). Moreover, the theory uses a constant force method to measure the percentage of the area of the mesh that, under strain, has a pore size of ***greater than*** 1 mm in all directions. Yet Dr. Klosterhalfen agreed that, unlike the force applied in these calculations, "[n]obody knows exactly" what the actual force is in the pelvic floor, but that it "most probably" is not constant. (Klosterhalfen 198:17-25). And by his own account, the mechanical aspect of pelvic floor repair "is much more important than the local tissue response and is one of the major reasons why meshes fail today," and that it remains an "unsolved" problem even in 2014. (Klosterhalfen 183:6-17, 212:18-22).

Nor is PVDF mesh for SUI an ***available*** or ***feasible*** alternative design. Dr. Klosterhalfen purported to be working now on a mesh for SUI that he believes will solve the biomechanical problems but did not divulge any details, citing confidentiality concerns. (Klosterhalfen 214:4-20). He admitted that there is no available design incorporating PVDF mesh for treating SUI:

> Q. And you're hoping that this confidential mesh will solve the problems that exist in the pelvic floor?
> A. That's true.
> Q. But you don't have that mesh available for us today, do you?
> A. No.

(Klosterhalfen 214:13-19). PVDF mesh is not available for human implantation in the United States. (Klosterhalfen 219:23-220:12). This falls woefully short of being available.[1] Finally,

[1] *See Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256-57 (Tex. 1999) ("***availability*** of a safer alternative design . . . [is] a requisite element of a cause of action for defective design"); *Merck & Co. v. Garza*, 277 S.W.3d 430, 440 (Tex. App. 2008) (claim failed because only evidence of safer alternative design was patent application for unapproved drug), *rev'd in part on other grounds*, 347 S.W.3d 256 (Tex. 2011); *Dyer*, 115 F. Supp. 2d at 739 (defendant entitled to judgment where expert could not "determine with any degree of certainty how safe or efficacious pedicle screws are in comparison to other ***available***, ***approved*** procedures"); *accord Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 401-02 (6th Cir. 1990); *Wolfe v. McNeil-*

Dr. Klosterhalfen never testified that PVDF mesh is "not unreasonably expensive" compared to, and "equally effective" as, TVT. *Dyer*, 115 F. Supp. 2d at 738; *see also Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 (Tex. 1998); *Smith*, 237 F.3d at 519-20. A jury cannot fill in the blanks to arrive at those conclusions on its own.

In sum, PVDF mesh is no more than the "preliminary concept" of an alternative design that the Fifth Circuit rejected in *Smith*, where the expert "was not ready to recommend [it] to a manufacturer" and conceded that it would be "somewhat awkward" to use. 237 F.3d at 519.

Ethicon hernia meshes. Plaintiff also appears to offer Vypro or Ultrapro, hernia meshes manufactured by Ethicon, as alternative designs on the ground that these meshes are lighter and have a larger pore size. (Klosterhalfen 46:15-22). However, none of Plaintiff's experts testified that these meshes would be safer than, and at least as effective as, TVT for the treatment of SUI.

Dr. Klosterhalfen admitted that it is "probable" that larger-pore meshes, when used to treat SUI, would have the same complications and may not even be successful. When asked whether a mesh like Vypro with a pore size of more than 3 mm – which, according to him, is the minimum to ensure 1 mm effective porosity – was sufficient for treating SUI, he testified that "I think this is a question I can't answer, because you have no meshes in that application, I believe." (Klosterhalfen 45:14-19, 180:19-20). He opined that "it could be rather probable that you will have the same complication [with the hernia meshes] than with a heavyweight mesh," and has "doubts whether this application, or meshes in this application are successful – will ever be successful or not." (Klosterhalfen 182:1-3, 182:12-19). This "fails to establish that the alternative design would have 'significantly' reduced the risk of . . . injury." *Smith*, 237 F.3d at 520; *see Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 433 (Tex. 1997) (no alternative

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PPC, Inc., 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011) (without FDA-approved alternative product, "there is no available alternative design of the drug for defendants to adopt") (all emphasis added).

design because injury would have occurred "regardless of whether" different design). Nor is there expert testimony that Vypro meets the "effective porosity" standard.

Modified Prolene. Plaintiff hints that Prolene itself could somehow be improved, but none of her experts testified to a reasonable degree of certainty that these supposed improvements would be equally effective and significantly reduce the risk of injury. As just shown, Plaintiff's own expert admits that larger pore, lighter weight mesh might not be suitable to treat SUI. In addition, Ethicon engineering fellow Dan Smith testified unequivocally that three other Ethicon meshes (Gynemesh PS, Ultrapro, and TVT-O partially absorbable) were neither safer than nor as effective as TVT in the treatment of SUI. (Smith 636:9-637:19; 637:23-639:9; 648:19-649:15).

Similarly, Plaintiff has offered no expert opinion that laser-cut mesh could be a safer alternative. Dr. Rosenzweig testified only that laser-cut mesh could prevent roping or curling (which no one has testified occurred in this case) and that it "might have less flaking and particle loss." (2/11 RT 79:22-25). Indeed, the only testimony on the efficacy issues is the testimony from Dr. Kammerer that:

- use of the laser cutting method does not affect tissue ingrowth or device functionality;
- mechanically cut mesh is not inferior and the two have the same attributes; and
- studies showed identical histology with no indication that there is any long-term difference between the two cutting methods.

(Kammerer 423:8-14, 424:19-24, 427:22-428:2). Dan Lamont, who was responsible for global postmarket safety surveillance at Ethicon, testified that trending report analyses did not show "a significant difference or any potential trend that would require investigation between" the two meshes. (Lamont 163:6-18). And to the extent Plaintiff relies on forced 50% elongation studies, those studies do not reflect in vivo use. (Kammerer 430:24-431:15). Finally, Plaintiff has failed

to prove that laser-cut mesh is a ***safer*** alternative design: even if it reduced particle loss or fraying, Plaintiff has not shown that these conditions are clinically significant.

Native tissue repair. Finally, a "native tissue repair" or "Burch procedure" cannot be a safer alternative design. "A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle," and the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market." *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995); *see also Schmidt v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 101963, at *5-6 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support [a design defect claim]."). Native tissue repair is no more an alternative "design" to TVT than a car is an alternative design to a motorcycle. And in any event, Dr. Rosenweig's equivocal testimony does not show that native tissue repair is safer than, and at least as effective as, TVT.[2]

III. Plaintiff Failed To Show That An Alleged Design Defect Caused Her Alleged Injury.

Even if all her theories about design defect were true, Plaintiff's claim fails because she has not shown that her injuries were caused by a defect in TVT's design. To reach a jury on her claim, Plaintiff must present expert testimony stating with "reasonable medical probability" that a particular design defect in TVT was a producing cause of her alleged injury; a mere possibility is insufficient. *Mack Trucks v. Tamez*, 206 S.W.3d 572, 583 (Tex. 2006); *Anderson v. Siemens Corp.*, 335 F.3d 466, 474-75 (5th Cir. 2003). Expert testimony is required because "the causal link is beyond the jury's common understanding." *Alexander v. Turtur & Assocs., Inc.*, 146

[2] Dr. Rosenzweig testified merely that the TVT surgery carried risks that the Burch procedure did not, but also testified that the converse was true. He acknowledged that the Burch procedure required general or spinal anesthesia (which obviously carries its own risk) and requires a larger incisions, which increases the risks of infection and bleeding and requires a longer hospital stay. (2/11 RT 115:13-20, 116:20-117:6). In addition, Dr. Rosenzweig acknowledged that one study found lower reoperation rates with TVT as compared with the Burch procedure. (2/11 RT 141:19-142:4).

S.W.3d 113, 119-120 (Tex. 2004).[3] Plaintiff's design theory requires her to present expert testimony that (1) the TVT's pore size, weight, fraying, particle loss, or degradation, (2) caused, to a reasonable medical probability, (3) her alleged pain, dyspareunia, or voiding dysfunction. Not one of Plaintiff's experts has so testified.

Dr. Bernd Klosterhalfen, a surgical pathologist, testified to supposed alternatives to TVT and the weight and pore size of TVT. He is not a gynecologist or urologist, did not examine Plaintiff, and did not speak to her alleged injuries. (Klosterhalfen 234:6-22).

Dr. Bruce Rosenzweig, a urogynecologist, testified that in ***other*** patients, he observed scarring, cracking, roping, fraying, curling, and particle loss. (2/11 RT 70:22-73:11, 75:4-6, 88:25-89:3). But he agreed that his opinions were ***not*** specific to Plaintiff, conceding he did not examine her or consult her physicians. (2/11 RT 127:21-128:1). Thus, he cannot carry Plaintiff's specific causation burden. *See Wal-Mart Stores, Inc. v. Merrell*, 313 S.W.3d 837, 40 (Tex. 2010) (expert's testimony "that halogen lamps can cause fires generally . . . does not establish that the lamp in question caused *this* fire") (emphasis in original).

Dr. Howard Jordi, a polymer chemist, is the only one of Plaintiff's experts to have inspected her mesh. He did not testify as to any fraying. He claims to have observed degradation, particle loss, and cracking in her explanted mesh. (2/12 RT 63:20-64:2, 65:18-66:2). But neither he nor any other witness testified that any degradation or particle loss injured Plaintiff.[4] In fact, he did not testify that alleged particle loss or degradation has any clinical

[3] By way of analogy, expert testimony was also required in the following cases: *Anderson*, 335 F.3d 466 (stroke and death allegedly caused by ventilator); *Burroughs Wellcome Co. v. Crye*, 907 S.W.2d 497 (Tex. 1995) (frostbite allegedly due to Polysporin spray); *Smith v. Southwestern Bell Tel. Co.*, 101 S.W.3d 698, 702 (Tex. App. 2003) (fibromyalgia); *Coastal Tankships, U.S.A., Inc. v. Anderson*, 87 S.W.3d 591, 603 (Tex. App. 2002) (bronchiolitis obliterans organizing pneumonia).

[4] No expert has testified that particle loss itself causes injury. And Dr. Gene Kammerer testified that, in his experience, any particles that flake during implantation are too soft to migrate through tissue, and the supposedly "sharp" edges of the TVT do not cause complications. (Kammerer 402:12-20).

significance at all. (2/12 RT 130:22-131:4). Dr. Jordi also admitted that he could not determine the extent or duration of the purported cracking in Plaintiff's explant, or even that cracking impacts functionality. (2/12 RT 128:19-129:3, 129:18-131:4).

Dr. Uwe Klinge, Dr. Klinge, an abdominal surgeon, could not conclude that a defect in the TVT caused Plaintiff's alleged injuries. Dr. Klinge did not examine Plaintiff or her mesh; he merely viewed pathology slides prepared by someone else. He testified that "the excessive scar formation that we have found to be the major cause of many complications, that this is found in these samples in this case, as well. We saw the scar formation, the deformation, the folding, the particle loss." (2/13 RT 89:24-16). However, in his 20 years of mesh research, he has never studied the clinical effects of particle loss. (2/13 RT 103:19-22). And he did not testify that Plaintiff's alleged injuries were, to a reasonable degree of medical certainty, caused by an alleged defect. (2/13 RT 91:4-92:2). Nor could he, as that is beyond his expertise.

Dr. Philippe Zimmern, the explanting surgeon, is the only one of Plaintiff's witnesses to actually have examined her. But he did not identify any property of the TVT – as opposed to the mere presence of a suburethral sling – responsible for her alleged pain. He did not identify any chronic inflammation from the mesh,[5] and though he acknowledged some scarring, he did not testify that it was "excessive" or abnormal for this type of surgery. That is exactly how he explained the TVT, as with other suburethral slings, is supposed to function: "the growth of the – of the scar into the weaves of the mesh," which "secures the mesh in place." (Zimmern 129:20-23). He did not opine on the cause of any voiding dysfunction. And as to the cause of the alleged pain and dyspareunia, he could say only that it was "the presence of the tape" but that "[b]y which mechanism in the tissue she hurts, that, I don't know." (Zimmern 95:4-18.) When

[5] Dr. Zimmern, when asked whether that pathologist's identification of a foreign body giant cell evidenced chronic inflammation, responded: "No. I think it's just evidence that there is a foreign body there." (Zimmern 127:8-12, 118:18-119:02).

pressed as to what property of the tape caused the pain, he testified: "It's anybody's guess. Could be muscle changes, nerve changes, innervation, nerve entrapment, tension. We really don't know the answer to that question." (Zimmern 99:33-8). This is insufficient: the inquiry is not whether the "***presence of the tape***" caused the alleged injuries, but whether a ***defect in the TVT design*** caused them. *See Romo*, 798 F. Supp. 2d at 806; *Duff v. Yelin*, 751 S.W.2d 175, 176 (Tex. 1988) ("Proof of mere possibilities will not support the submission of an issue to the jury."). Dr. Zimmern leaves open the possibility that the injuries were caused by physician error or some other cause, as opposed to the purported defects described by Plaintiff's experts.

All told, no expert has testified, to a reasonable degree of medical certainty, that a defect in the TVT design caused Plaintiff's alleged injuries. But "[t]o establish specific causation . . . ***an expert*** must demonstrate a 'specific train of medical evidence' connecting the illness to the product." *Newton v. Roche Labs.*, 243 F. Supp. 2d 672, 682 (W.D. Tex. 2002) (emphasis added). This case is thus unlike *Cisson*, where the Court denied a Rule 50(b) motion because an expert "testified two separate times to a reasonable degree of medical certainty that Ms. Cisson's pain was caused by the mesh, and specifically by the placement of the arms." *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, Doc. 448, p. 6 (S.D. W. Va. Oct. 18, 2013).

CONCLUSION

For the foregoing reasons, Ethicon respectfully submits that Plaintiff has failed to carry her burden of proof as to any element of her claim.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on February 17, 2014, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this case.

/s/ Christy D. Jones
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